[redacted]

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/394,712	09/13/99	ESMOND	R 0609.4440002

HM12/0925

ROBERT W ESMOND
312 BLAIR COURT NW
VIENNA VA 22180

EXAMINER	
KIM, V	
ART UNIT	**PAPER NUMBER**
1614	6

DATE MAILED: 09/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/394,712	Esmond et al
Examiner	**Group Art Unit**
Vickie Kim	1614

☐ Responsive to communication(s) filed on _____ .

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-8 and 13-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-8 and 13-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4-5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-8 and 13-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating Alzheimer's disease, does not reasonably provide enablement for preventing Alzheimer's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. "Prevention of Alzheimer's disease" is not credible in the real practice because outright prevention of Alzheimer's disease could not be achievable. One of skilled artisan would not expect that Alzheimer's disease is preventable disease.

This rejection would be obviated if these claims are limited to treatment of Alzheimer's disease.

Allowable Subject Matter

3. Claims 2, 8 and 13-20 contain allowable subject matter.

4. The claims 8 and 13-20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Maack et al (WO 9513823), Baker et al (US 5,534,615), Klein et al (US 6,025,157) or Rosenthal (US 5,364,769).

The claims read on a method of treating Alzheimer's disease comprising administering an effective amount of insulin-like growth factor.

First, Maack et al teach all the critical element in their patented reference; see claim 1.

Secondly, Baker et al, Klein et al or Rosenthal, each patentee acknowledges that insulin-like growth factor which is a neurotrophic factor, enhances neuronal survival and growth as a treatment for neurodegenerative disease such as Alzheimer's disease; see US'615(column 2,

lines 39-45), US'157 (column 1, lines 28-35) and US'769(column 2, lines 10-15 and column 3, lines 38-41).

It is noted that increasing insulin sensitivity of the human is inherently possessed when an insulin-like growth factor is administered in Alzheimer's patient. The support for the said inherent feature is apparently available in the art. For instance, Clark et al (US 5,783,556) teach insulin-like growth factor (RhIGF-I) has ability to improve insulin sensitivity; see column 3, line 50. Moses et al (US 5,612,312) also teach insulin-like growth factor (IGF-I) reverses insulin resistance wherein insulin resistance is defined as high blood glucose levels, markedly elevated serum insulin levels, and insensitivity to insulin:see column 7, lines 30-40 and column 8, lines 20-23.

Thus the claimed subject matter is not patentably distinct.

6. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenthal (US 5,364,769) or Dubach et al (WO 96/03087).

The claims read on a a method of treating Alzheimer's disease comprising administering an effective amount of dopamine agonist.

Rosenthal (and cited reference thereof) or Dubach et al, each patentee acknowledges the fact wherein dopamine agonist has been used to treat Alzheimer's disease; see US'769 (column 17, lines 14-18) and WO'087 (column 6, lines 29-34).

It is noted that increasing insulin sensitivity of the human is inherently possessed when a dopamine agonist is administered in Alzheimer's patient.

7. Claims 1 and 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Grainger et al (US 6117911).

The claims read on a a method of treating Alzheimer's disease comprising administering an effective amount of thiazolidenediones such as troglitazone.

Grainger et al teach all the critical element in their patented reference;see column 1, line 66 thru column 2, line 2, and column 14, lines 31-35.

Grainger et al teach that thiazolidenediones(e.g.troglitazone) which increases transforming growth factor-beta (TGF-beta) level is useful to treat Alzheimer's disease; see column 8, lines 59-65 and column 13, lines 55-60.

It is noted that increasing insulin sensitivity of the human is inherently possessed when thiazolidenediones(e.g.troglitazone) is administered to treat Alzheimer's disease.

Thus the claimed subject matter is not patentably distinct.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) a patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal (US 5,364,769) or Dubach et al (WO 96/03087), each in view of Michaelides et al (US 5,597,832).

Rosenthal or Dubach et al' teaching was mentioned immediately above.

Applicant's claim differs because it additionally requires bromocriptine.

However it would have been obvious to one of ordinary skill in the art to substitute a dopamine agonist with bromocriptine when their teaching is modified with Michaelides et al's

references because Michaelides et al teach bromocriptine is the most widely used direct-acting dopamine agonist.

One would have been motivated to do so, with reasonable expectation of success, because bromocriptine is easily accessible, and the efficacy and side effects are well proven since it had been around for a long time.

One would have been motivated to combine these references because they are analogous and drawn to same technical field.

Conclusion

12. All the pending claims are rejected.

13. However, the claims 2,8 and 13-20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Vickie Kim* whose telephone number is **(703) 305-1675** (Monday-Thursday: 7AM-6PM) and Fax number is (703) 308-7924.

Vickie Kim,

Patent examiner

September 14, 2000

SUPERVISORY PATENT EXAMINER
GROUP 120

William Jarvis

Primary examiner

Art unit 1614